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DETAILED ACTION

1. Applicant's amendment, remarks, and IDS, filed 3/14/08 are acknowledged.
2. Claims 39 and newly added Claims 61-83 are under examination.
3. In view of Applicant's amendment, all previous rejections have been withdrawn. The following are new grounds for rejection necessitated by Applicant's amendment.
4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 39 and 61-83 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/41813 (IDS).

WO 01/41813 teaches a method of stabilizing or improving the health-related quality of life of an individual with SLE comprising administering LJP-394 at a dose of about 5-100mg/kg, or about 200-500 mg (see particularly page 40). LJP-394 comprises the dsDNA epitope of SEQ ID NO:1 and SEQ ID NO:2 conjugated to the valency platform of Claim 71 (see particularly the Claims). The reference teaches the additional limitations of the claims including sustained reduction of symptoms for at more than about 16 or 24 weeks, or a year (Figures 14 and 15). The figures also show an at least about 20% or 30% reduction below baseline. Note that Claim 81 does not recite the actual use of SF-36 to measure stabilization or improvement but only that said stabilization of improvement is detectable, i.e., could be detected, employing said form. Regarding the "assessing" and "selecting" steps now recited in the claims, said steps are necessarily a part of treatment of SLE by a physician. The patient goes to the physician, the physician "assesses" disease and "selects" a patient in need of treatment, and the physician treats the patient. Regarding the ongoing treatment limitations of Claims 62, 64, and 66, said limitations are taught by the reference as the reference teaches patients

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that "continue to receive treatment" (page 11) and, indeed, the term "receiving treatment" is defined as including "continuing treatment" (page 19). Finally note that the "adjusted dosage" limitation of Claim 66 is implicit in the teaching of administering "a sufficient amount", e.g., as taught at page 24 of the reference. Accordingly said claims are included in the rejection.

The reference clearly anticipates the claimed invention.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 39 and 61-83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-64 of U.S. Patent No. 7,081,242. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '242 patent encompass a method of treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2.

In response to a previous rejection Applicant argues that the '242 patent does not contain the "slightest hint or suggestion" of the stabilization, improvement, or assessment of the claimed method.

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It is reasonably obvious to a physician to assess patients and treat so as to achieve their stabilization and improvement.

8. Claims 39 and 61-83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-26 of U.S. Patent Application No. 10/814,555. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '555 application encompass a method of treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 39 and 61-83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-39 of U.S. Patent Application No. 11/081,309. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '309 application encompass a method of treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 39 and 61-83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-27 of U.S. Patent Application No. 11/347,426. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '426 application encompass a method of treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 39 and 61-83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-21 and 34-55 of U.S. Patent Application No. 11/373,699. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '699 application encompass a method of

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treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 39 and 61-83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-26 of U.S. Patent Application No. 11/565,467. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '467 application encompass a method of treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 39 and 61-83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-39 of U.S. Patent Application No. 11/562,174. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '987 application encompass a method of treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Regarding sections 8-13 above, in response to previous similar rejections, Applicant again requests that the provisional rejections be withdrawn.

The provisional rejections set forth above are proper for the reasons set forth above.

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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15. Claims 72 and 73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter written description rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

- a) a method ... administering a dose of about 5 mg/kg to about 100 mg/kg of the individual (Claim 72).
- b) a method ... administering a dose of about 200 mg to about 500 mg (Claim 73).

Applicant cites paragraph [219] for support and further cites *In re Werthheim*.

There appears to be no question that paragraph [219] does not disclose the specific dosage ranges of the claims. Applicant appears to argue that in view of *In re Werthheim*, any range Applicant might choose would be acceptable. Indeed, by Applicant's logic if an application disclosed a range of from 0 to infinity any range in between could then be claimed. *In re Werthheim* discloses a very narrow range that is further limited at the lower end to a disclosed example. This is not the situation in the instant case.

16. No claim is allowed.

17. Applicant's amendment or action necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, Ph.D. can be reached on (571) 272-0878.

19. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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